STATE OF WASHINGTON
WASHINGTON STATE BOARD OF HEALTH
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October 15, 2003

To: Washington State Board of Health Members

From: Tom Locke, Board Member, Chair, Newborn Screening Advisory Committee

RE: CHAPTER 246-650 WAC—NEWBORN SCREENING RULE ADOPTION

Background and Summary

RCW 70.83.020 mandates that newborns be screened for "phenylketonuria and other heritable or metabolic disorders…as defined by the state board of health." Chapter 246-650 WAC, a Board rule, defines the required screenings. It currently requires universal newborn screenings for three disorders in addition to phenylketonuria (PKU)—congenital hypothyroidism, congenital adrenal hyperplasia, and hemoglobinopathies such as sickle cell disease.

At today's meeting, the Board will hold a public hearing on proposed revisions to the Newborn Screening rules: Chapter 246-650. The changes would:

- Require screenings for five additional metabolic disorders recommended by the Newborn Screening Advisory Committee—biotinidase deficiency, galactosemia, homocystinuria, medium chain acyl co-A dehydrogenase deficiency, and maple syrup urine disease;
- Incorporate privacy requirements recommended by the Genetics Advisory Committee;
- Specify that implementation of new screenings must begin by January 1, 2004.

Contingent on oral or written comments the Board receives and subsequent Board discussion, I would suggest the Board adopt the proposed rule change to the Newborn Screening WAC with some technical amendments I am recommending (attached). I also recommend that the Board:

- Ask the Department of Health (DOH) to continue to track and encourage current hospital efforts to voluntarily adopt universal newborn hearing screening, and to report back to the Board in spring 2004;
- Consider reconvening an advisory committee in the near future to evaluate current information on newborn screening for cystic fibrosis, early hearing loss, and other disorders.

Proposed Board Action

Contingent on oral and written public testimony as well as Board discussion, I propose the Board adopt the revisions to Newborn Screening Chapter 246-650 WAC published in the Washington State Register as WSR 03-17-092, incorporating by amendment any changes it deems necessary. I also suggest the Board adopt the following motion:

The Board authorizes the Chair to send a letter to Secretary Selecky supporting the Department of Health's continued efforts to track newborn hearing rates and to encourage hospitals to voluntarily implement universal newborn hearing screening.

Discussion

RCW 70.83.020 mandates that newborns be screened for "phenylketonuria and other heritable or metabolic disorder leading to mental retardation or physical defects as defined by the state board of health." It includes a religious exemption. Chapter 246-650 WAC, a Board rule, defines the conditions for which newborns must be screened. It currently requires screenings for phenylketonuria, congenital hypothyroidism, congenital adrenal hyperplasia, and hemoglobinopathies such as sickle cell disease.

In 2001, the Board, in collaboration with the DOH, initiated a review of Chapter 246-650 WAC. The agencies convened a broad-based advisory committee to assist with this effort. In May 2002, the Newborn Screening Advisory Committee recommended specific criteria for the Board to use when evaluating which disorders are candidates for universal screening. Based on those criteria, the committee also recommended that the Board add five metabolic disorders and newborn hearing loss to the list of disorders for which screening is required. The metabolic disorders are biotinidase deficiency, galactosemia, homocystinuria, medium chain acyl co-A dehydrogenase deficiency, and maple syrup urine disease.

Because the Board wanted to allow lawmakers to address funding issues, it accepted the advisory committee's report but chose to wait until after the 2003 legislative session before proposing any specific rule changes. The 2003-2005 state budget passed by the Legislature included authority to increase the newborn screening fee in excess of the Initiative 601 limit in order to cover the cost of the five additional blood tests ($2.35 million). It also included funding to cover Medicaid costs that will be incurred by the state when these tests are mandated ($848,000). It did not include authority to collect and spend fees for newborn hearing screening. The Department of Health did receive funding ($222,000 general fund-state) to support surveillance and tracking activities help hospitals achieve universal coverage under the current voluntary system.

Following the session, DOH and the Board began working on draft rules. The Board filed the CR-102 Proposed Rules on August 20, 2003 (WSR 03-17-092). The published proposal would require screenings for all five recommended metabolic disorders. It would not require newborn hearing screening hearing. During the comment period, one individual recommended that three disease definitions be clarified. DOH also noted that there are instances under law where blood spot specimen information must be disclosed and recommended the privacy section of the rule reflect that. I have attached a package of amendments that would incorporate the recommended changes into the proposed rule.

I suggest that the Board authorize Chair Linda Lake to send a letter to Secretary Selecky supporting DOH's continued efforts to track newborn hearing rates and encourage all hospitals to voluntarily implement universal newborn hearing screening. I also suggest that the Board ask DOH to provide a progress report to the Board in spring 2004. In the near future, possible as early as spring 2004, I will probably ask that the Board reconvene an advisory committee and charge it with using the established criteria to evaluate the most current information on newborn screening for cystic fibrosis, early hearing loss, and other possible disorders.

Attachment